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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/016,869	01/30/98	BEACH	D 071.10

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EXAMINER	
TUNG, M	
ART UNIT	PAPER NUMBER
1644	24

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Advisory Action

Application No.	Applicant(s)
09/016,869	Beach, et al.
Examiner	**Art Unit**
Mary B. Tung	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Oct 26, 2000* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *Mar 3, 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s): _____

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached _____

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: _____

   Claim(s) objected to: _____

   Claim(s) rejected: *11 and 58-78* _____

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

11. ☐ Other:

Supplement to Advisory Action

1. Claims 1-57 were originally presented.

2. Claims 2-9 and 12-57 were cancelled in the amendment filed 10/7/98, Paper No. 7.

3. Claims 58-76 were added in Paper No. 7.

4. Claims 77 and 78 were added in the paper filed 3/23/00, Paper No. 12.

5. Claims 1 and 10 stand non-elected.

6. Claims 11 and 58-78 are under consideration.

NOTE: the Applicant improperly cancelled claims 1 and 10 in the paper filed 10/25/2000, paper No. 18. The direction by Applicants to cancel claims must be included in the section entitled "In the claims". Therefore, claims 1 and 10 remain non-elected pending claims.

Claim Rejections - 35 U.S.C. § 102

7. Claims 11, 58-61 and 65-67 and new claims 77 and 78 stand rejected under 35 U.S.C. 102(e) as being anticipated by Skolnick, et al. *(US Patent No. 5,624,819).*

Applicant submitted the specification from parent case 08/154,915, previously unavailable to the Examiner. The Applicants directed the Examiner to page 6, line 15-17, page 25, lines 24-25 and page 28, lines 14-23 of the '915 specification as support for the instant pending claims. The pending claims, such as claim 11, are drawn to an antibody specific for a genus of cyclin dependent kinase, whereas the '915 patent merely provides support for antibodies specific for p16 (see page 28, line 15) and more particularly, raised against the GST-p16INK4 fusion protein (see page 25, lines 24 and 25). The antibody to a species of polypeptide cannot provide support for the entire genus of antibodies, as claimed herein. Therefore, Skolnick, et al. is not overcome by the '915 parent specification.

Claim Rejections - 35 U.S.C. § 103

8. Claims 11 and 58-76 and new claims 77 and 78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Skolnick, et al. *(US Patent No. 5,624,819).*

Applicant submitted the specification from parent case 08/154,915, previously unavailable to the Examiner. The Applicants directed the Examiner to page 6, line 15-17, page 25, lines 24-25 and page 28, lines 14-23 of the '915 specification as support for the instant pending claims. The pending claims, such as claim 11, are drawn to an

antibody specific for a genus of cyclin dependent kinase, whereas the '915 patent merely provides support for antibodies specific for p16 (see page 28, line 15) and more particularly, raised against the GST-p16INK4 fusion protein (see page 25, lines 24 and 25). The antibody to a species of polypeptide cannot provide support for the entire genus of antibodies, as claimed herein. Therefore, Skolnick, et al. is not overcome by the '915 parent specification. The office position is consistent with MPEP 201.11.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 65, 77 and 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Claims 65, 77 and 78 recite a preparation of polyclonal antibodies, wherein a CCR protein is at least 80%, 90% or 95% identical to SEQ ID NOS: 2, 4 or 6, respectively. The specification fails to disclose any common essential features that an amino acid sequence having 80 %, 90% or 95 % sequence identity with SEQ ID NOS: 2, 4 or 6 would possess. The essential element of the invention is the characteristics of the CCR polypeptide, however, the Applicants have not provided disclosure in the specification as to the structure and function relationship that is essential to the claimed antibody to the CCR. The specification and claims do not indicate what distinguishing attributes are shared by the members of the claimed genus. The scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and the claims do not provide any guidance as to what changes should be made or what structural features that could distinguish compounds in the genus from others in the genus are missing from the disclosure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, SEQ ID NOS: 2, 4, or 6 alone is insufficient to describe the genus or the claimed methods. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

12. The Applicants argue that the specification provides a representative number of species

falling within the broad genus and identifies that they have common features, such as having four ankyrin repeats and binding to cyclin-dependent kinases. The Applicants further argue that their position is supported in *University v. Eli Lily and Co., 19 F.3d 1559, 43 USPQ.2d 1398,* Federal Circuit (1997). However, in *University v. Eli Lily and Co., 19 F.3d 1559, 43 USPQ.2d 1398,* the Federal Circuit (1997) ruled *(§ 115.1103; pages 1399, 1405 and 1406)* that a "Patent specification does not provide adequate written description of claimed microorganism containing human insulin-encoding cDNA, since patent includes example providing process for obtaining human insulin-encoding cDNA, and describes protein that cDNA encodes, but provides no further information, such as sequence information indicating which nucleotides constitute human cDNA, pertaining to that cDNA's relevant structure or physical characteristics.... DNA is not made obvious by mere knowledge of desired protein sequences and methods for generating DNA that encodes that protein, and since description that does not render claimed invention obvious therefore does not sufficiently describe that invention for purposes of 35 U.S.C. 112.... In claims to genetic material, generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others; accordingly, naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material. **The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.** *See In re Wilder , 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)* (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." The instant claims read on antibodies specifically reactive with a cell regulatory protein. The written description in the specification, however, discloses only a limited number of species, mostly fragments, besides the human sequence of p16. The specification has not described the breadth of the claimed invention in view of the teachings of the specification. The state of the art is such that it is unpredictable from the data disclosed in the specification as to whether (and how) the "cell regulatory protein" in the instant invention could be used. The arguments by Applicants that the non-disclosed species have "80%, 90% or 95% with the disclosed human sequence does not satisfy 35 U.S.C. 112 in light of *U.C. v. Eli Lily*, because the disclosed species do not distinguish a genus from the others except by function and that the description of the disclosed sequence does not render the claimed mammalian sequences obvious. Although *U.C. v. Eli Lily* addresses DNA in particular, the instant claimed invention is encompassed by the ruling in that the disclosure of one amino acid sequence would not describe a specific sequence of

another primate animal as recited, and thus is encompassed by the case. Therefore, the rejection stands.

13. Applicant is directed to the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday, January 5, 2001. In keeping with the written description guidelines and corresponding training materials (available on the PTO Website), the claimed invention lacks adequate written description in the specification.

Conclusion

14. This application contains claims 1 and 10, drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 C.F.R. 1.144) See MPEP § 821.01.

15. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

April 11, 2001
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640